



## UNITED STATES PATENT AND TRADEMARK OFFICE

DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BOARD OF PATENT APPEALS AND INTERFERENCES  
BOX INTERFERENCE, WASHINGTON, D.C. 20231

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MAILED

MAR ~ 2 2006

PAT. & T.M. OFFICE  
BOARD OF PATENT APPEALS  
AND INTERFERENCES

Applicants: Branstrom et al.  
Application No.: 09/512,810  
Filed: 02/25/00  
For: Bacterial delivery system

The above-identified application or patent has been forwarded to the Board of Patent Appeals and Interferences because it is adjudged to interfere with another application or patent. An interference has been declared. The interference is designated as No. 105,428.

Notice is hereby given the parties of the requirement of the law for filing in the Patent and Trademark Office a copy of any agreement "in connection with or in contemplation of the termination of the interference." 35 U.S.C. § 135(c).

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Fred E. McKelvey  
Senior Administrative Patent Judge

The opinion in support of the decision being entered today is not binding precedent of the board.

Paper 1

Filed by:

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Senior Administrative Patent Judge  
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Filed 2 March 2006

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES  
(Senior Administrative Patent Judge McKelvey)

ARTHUR A. BRANSTROM, DONATA R. SIZEMORE  
and JERALD C. SADOFF,

Junior Party  
(Application 09/512,810),

v

ROBERT J. POWELL, GEORGE K. LEWIS  
and DAVID M. HONE,

MAILED

MAR 2 - 2006

PAT. & T.M. OFFICE  
BOARD OF PATENT APPEALS  
AND INTERFERENCES

Senior Party  
(Patent 5,877,159).

Patent Interference 105,428 (McK)  
Technology Center 1600

## **DECLARATION**

37 CFR § 41.203(b)

**Part A.**  
**Declaration of interference**

1. An interference is declared between the identified parties. 35 U.S.C. § 135(a); 37 CFR 1.18(b).

1                   2. Details of the application, patent, counts and  
2 claims designated as corresponding or as not corresponding to the  
3 counts appear in Parts E and F of this DECLARATION.

**Part B.**  
Judge managing the interference

7 Senior Administrative Patent Judge McKelvey has been  
8 designated to manage the interference. 37 CFR § 41.104(a).

**Part C.  
Standing order**

12                   1. A Trial Division STANDING ORDER (3 Jan. 2006)  
13 (Paper 2) accompanies this DECLARATION.

14                   2. The STANDING ORDER applies to this interference,  
15 including the provisions related to Electronic Filing. See  
16 ¶ 105, pages 17-20.

**Part D.**  
**Initial conference call and motions lists**

## Conference call

21                   1. A conference call to discuss the interference is  
22                   set for:

4:00 p.m. (1600 hours Eastern time)  
on Wednesday, 26 April 2006.

? The board will initiate the call.

## Motions lists

28                           3. On or before:

31 5:00 p.m. (1700 hours Eastern time) Friday, 21 April 2006,

1 each party shall serve, a notice stating the relief the party  
2 requests, i.e., a motions list including motions the party seeks  
3 authorization to file. 37 CFR § 41.120(a); STANDING ORDER ¶ 204,  
4 (Paper 2, page 58).

5                   4. The default procedure for filing and serving its  
6 motions lists are to be filed before being served.

7               5. By filing before service, one party will not have  
8 access to an opponent's motions list prior to filing the party's  
9 motions list.

10                   6. Nevertheless, the parties may mutually agree to  
11 discuss and serve motions lists at any time prior to the date and  
12 time motions lists are due.

13                   7. The following shall be included in any motions  
14                   list:

- (1) Proposed motion for benefit must identify the application(s) for which benefit will be sought.
  - (2) Proposed motion to attack benefit must identify the application(s) being attacked.
  - (3) Proposed motion seeking judgment against an opponent based on alleged unpatentability must identify the statutory basis for the alleged unpatentability and:
    - (a) if based on the prior art, identify the prior art;
    - (b) if based on the first paragraph of 35 U.S.C. § 112, identify whether

- written description, enablement and/or  
best mode will be the basis of the  
proposed motion;
- (c) if based on no interference-in-fact,  
briefly identify the reason;
- (d) if based on an alleged failure to comply  
with 35 U.S.C. § 135(b), briefly  
identify the reason;
- (e) if claim correspondence is involved,  
identify any claim to be designated as  
corresponding or not corresponding to  
the count;
- (f) if a new count is to be sought, identify  
the new count.

8. A motions list shall not contain any "reservation  
clause" whereby a party attempts to reserve a right to file  
additional motions. Additional motions are those authorized by  
the board consistent with the rules.

9. A sample schedule for taking action during the  
motion phase appears as Form 2 (page 69) in the STANDING ORDER.

10. Counsel are encouraged to discuss the schedule  
prior to the conference call and to agree, essentially consistent  
with the sample schedule, on dates for taking action.

11. A typical motion period lasts approximately eight  
(8) months.

12. Counsel should be prepared to justify any request  
for a shorter or longer period.

Part E.  
Identification of the parties  
Assignment of exhibit numbers  
Initiating settlement discussions

## Junior Party<sup>1</sup>

Named inventors: Arthur A. Branstrom, Maryland  
Donata R. Sizemore, Maryland  
Jerald C. Sadoff, Washington, D.C.

Application:<sup>2</sup> Application 09/512,810  
filed 25 February 2000

Title: Bacterial delivery system

Assignee: United States of America as represented  
by the Secretary of the Army

<sup>1</sup> The junior party is the party with the latest accorded priority date as set out in this DECLARATION. 37 CFR § 41.201 (definition of "Senior party"); 37 CFR § 41.207(a)(1).

<sup>2</sup> The file is an Image File Wrapper (IFW), not a paper file.

### Senior Party<sup>3</sup>

Named inventors: Robert J. Powell, Maryland  
George K. Lewis, Maryland  
David M. Hone, Maryland

Patent:<sup>4</sup> U.S. Patent 5,877,159  
issued 2 March 1999  
based on application 08/443,790  
filed 3 May 1995

Title: Method for introducing and expressing genes in animal cells and live invasive bacterial vectors for use in the same

Assignee: University of Maryland at Baltimore

<sup>3</sup> The senior party is the party with the earliest accorded priority date as set out in this DECLARATION. 37 CFR § 41.201 (definition of "Senior party"); 37 CFR § 41.207(a)(1).

<sup>4</sup> The file is a paper file, not an Image File Wrapper (IFW) file. The first maintenance fee was paid on 25 July 2002. See the enclosed RAM Fee History for the patent. The second maintenance fee is not yet due.

**Assignment of exhibit numbers  
37 CFR § 41.154(c)(1)**

1. The senior party [Powell] is assigned exhibit

1001-1999

2. The junior party [Branstrom] is assigned exhibit

2001-2999

3. If necessary, the board will use exhibit numbers:

3001-3999

Initiating settlement discussions  
STANDING ORDER ¶ 126.1 (Paper 2, pages 40-41)

4. The senior party is responsible for initiating discussions.

Part F.

Count 1

A method for introducing and expressing a nucleic acid in animal cells in vitro comprising infecting said animal cells with live attenuated invasive bacteria selected from the group consisting of *Shigella* spp, *Listeria* spp and enteroinvasive *Escherichia coli*,

[1] wherein said bacteria includes a eukaryotic expression cassette containing said nucleic acid,

[2] wherein said nucleic acid encodes an antigen, and

[3] wherein said antigen is expressed at detectable levels.

Count 1 is similar to and modeled after Branstrom claim 45 and Powell claim 1. The following shows what was deleted from and added to the claims, with the matter in strikeout deleted and the matter in brackets added.

A method for introducing and expressing a gene [nucleic acid] in animal cells [in vitro] comprising infecting said animal cells with live [attenuated] invasive bacteria [selected from the group consisting of Shigella spp, Listeria spp and enteroinvasive Escherichia coli],

[1] wherein said bacteria contain [includes] a eukaryotic expression cassette encoding [containing<sup>5</sup>] said gene [nucleic acid],

[2] wherein said gene [nucleic acid] encodes a vaccine  
[an] antigen<sup>6</sup>, [and]

The cassette contains the nucleic acid; it does not encode it.

<sup>6</sup> The phrase "vaccine antigen" seems somewhat peculiar; the vaccine the composition administered and the object of administering the composition is to produce an antigen.

- 1           [3] wherein said vaccine antigen is expressed at  
2           detectable levels, and  
3           [4] ~~wherein said animals cells are cultured in vitro.~~

1  
2                   Count 2  
3  
4  
5  
6  
7

A method for introducing an immune response in an animal comprising infecting said animal with attenuated live invasive bacteria selected from the group consisting of Shigella spp, Listeria spp and enterioinvasive Escherichia coli,

[1] wherein said bacteria includes a eukaryotic expression cassette containing a nucleic acid,

[2] wherein said nucleic acid encodes an antigen,

[3] wherein said antigen is expressed at levels sufficient to induce an immune response, and

[4] wherein said invasive bacteria are administered to a mucosal surface of said animal.

Count 2 is similar to and modeled after Branstrom claim 53 and Powell claim 15. The following shows what was deleted from and added to the claims, with the matter in strikeout deleted and the matter in brackets added. In addition, it is noted that neither Branstrom claim 53 nor Powell claim 15 contains an antecedent for "said gene" in the phrase "encoding said gene" in the language in each claim which corresponds to that of paragraph [1], supra.

A method for introducing an immune response in an animal comprising infecting said animal with attenuated live invasive bacteria [selected from the group consisting of Shigella spp, Listeria spp and enterioinvasive Escherichia coli],

[1] wherein said bacteria ~~contain~~ [includes] a eukaryotic expression cassette ~~encoding said gene~~ [containing a nucleic acid],

1               [2] wherein said gene [nucleic acid] encodes a ~~vaccine~~  
2 an antigen,

3               [3] wherein said ~~vaccine~~ antigen is expressed at  
4 levels sufficient to induce an immune response, [and]

5               [4] wherein said invasive bacteria are administered to  
6 a mucosal surface of said animal.

1           The claims of the parties are:

2           Branstrom:     34-35, 37, 39 and 45-59

3           Powell:       1-24

4           The claims of the parties which correspond to Count 1 are:

5           Branstrom:     45-52

6           Powell:       1-6, 9-14 and 16

7           The claims of the parties which do not correspond to Count 1

8           are:<sup>7</sup>

9           Branstrom:     34-35, 37, 39 and 53-59

10          Powell:       7-8, 15 and 17-24

11          The parties are accorded the following priority benefit for

12          Count 1:

13          Branstrom:     None<sup>8</sup>

14          Powell:       None

---

16          <sup>7</sup> A claim which does not correspond to any count is not involved in  
17          the interference within the meaning of 35 U.S.C. § 135(a).

18          <sup>8</sup> Branstrom claims benefit of

19           (1) application 08/711,961, filed 06 September 1996 (an IFW file),  
20           (2) provisional application 60/018,035, filed 21 May 1996 (a paper  
21           file);  
22           (3) application 08,523,855, filed 06 September 1995, now U.S. Patent  
23           5,824,538, issued 20 October 1998 (a paper file) and  
24           (4) provisional application 60/00,3,318, filed 06 September 1995 (a  
25           paper file).

26          At this time, it has not been necessary to determine whether benefit should  
27          be accorded as to Count 1 because Branstrom has been placed under an order  
28          to show cause why judgment should not be entered against it under 37 CFR  
29          § 41.202(d)(2). In the event Branstrom overcomes the order to show cause  
30          and wants to be accorded benefit of one or more of the above-identified  
31          applications, Branstrom may list a motion for benefit in its lists of motions.

1           The claims of the parties which correspond to Count 2 are:

2           Branstrom:       53-59

3           Powell:          15 and 17-23

4           The claims of the parties which do not correspond to Count 2

5           are:<sup>9</sup>

6           Branstrom:       34-35, 37, 39 and 45-52

7           Powell:          1-14, 16 and 24

8           The parties are accorded the following priority benefit for

9           Count 1:

10           Branstrom:       None<sup>10</sup>

11           Powell:          None

---

13           <sup>9</sup> A claim which does not correspond to any count is not involved in  
14           the interference within the meaning of 35 U.S.C. § 135(a).

15           <sup>10</sup> Branstrom claims benefit of

16           (1) application 08/711,961, filed 06 September 1996 (an IFW file),  
17           (2) provisional application 60/018,035, filed 21 May 1996 (a paper  
18           file);  
19           (3) application 08,523,855, filed 06 September 1995, now U.S. Patent  
20           5,824,538, issued 20 October 1998 (a paper file) and  
21           (4) provisional application 60/00,3,318, filed 06 September 1995 (a  
22           paper file).

23  
24           At this time, it has not been necessary to determine whether benefit should  
25           be accorded at to Count 2 because Branstrom has been placed under an order  
26           to show cause why judgment should not be entered against it under 37 CFR  
27           § 41.202(d)(2). In the event Branstrom overcomes the order to show cause  
28           and wants to be accorded benefit of one or more of the above-identified  
29           applications, Branstrom may list a motion for benefit in its lists of motions.

**Part G.**  
**Heading to be used on papers**

The following heading must be used on all papers filed in this interference. STANDING ORDER ¶ 106.1.1 (Paper 2, page 20).

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES  
(Senior Administrative Patent Judge McKelvey)

(Senior Administrative Patent Judge McKelvey)

ARTHUR A. BRANSTROM, DONATA R. SIZEMORE  
and JERALD C. SADOFF,

Junior Party  
(Application 09/512,810),

v.

ROBERT J. POWELL, GEORGE K. LEWIS  
and DAVID M. HONE,

Senior Party  
(Patent 5,877,159).

Patent Interference 105,428 (McK)  
Technology Center 1600

**Part H.**  
**Order form for requesting file copies**

3                   1. When requesting copies of files, a party shall  
4       use STANDING ORDER Form 4 (page 71).

5                   2. Use of Form 4 will expedite processing of any  
6 request.

7                   3. A party should attach to any request for file  
8 copies a photocopy of Part E of this DECLARATION with a  
9 hand-drawn circle around the patents and applications for which a  
10 copy of a file wrapper is requested.

11                   4. The parties are advised that a single order for  
12 files may be filled by the Office of Public Records at more  
13 than one time, particularly in a case such as this one involving  
14 both paper and IFW files. STANDING ORDER ¶ 109.2 (Paper 2,  
15 pages 25-27).

## **Part I.**

## **Required paragraph for affidavits and declarations**

1. The board has experienced cases in which a witness has belatedly advanced reasons why the witness would be unable to appear for cross examination at a reasonable time and place in the United States.

2. Consequently, to prevent surprise and hardship to the party relying on the testimony of the witness, the following paragraph must be included on the signature page of all affidavits (including declarations) filed in this case .

STANDING ORDER ¶ 157.2 (Paper 2, pages 52-53):

In signing this affidavit (declaration), I understand that the affidavit (declaration) will be filed as evidence in a contested case before the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office. I also acknowledge that I may be subject to cross examination in the case and that cross examination will take place within the United States. If cross examination is required of me, I will appear for cross examination within the United States during the time allotted for cross examination.

/ss/Fred E. McKelvey

FRED E. MCKELVEY.

Senior Administrative Patent Judge<sup>12</sup>

2 March 2006  
Entered at: Alexandria, VA

<sup>12</sup> As part of board efforts under the government Paperwork Elimination Act, signatures on papers originating from the board have been phased out in favor of a completely electronic record. Consequently, in this case papers originating at the board will not have signatures. The signature requirements for the parties have not changed. See, e.g., 37 CFR § 10.18 (2005).

1      Enc:

2  
3      STANDING ORDER (3 Jan. 2006) (Paper 2)  
4      NOTICE OF REQUEST FOR ASSISTANCE ON TECHNOLOGY  
5                and ORDER (Paper 3)  
6      ORDER TO SHOW CAUSE (Paper 4)  
7      NOTICE TO DEPARTMENT OF JUSTICE (Paper 5)

8  
9      The following additional documents (1) are provided to  
10     permit the parties to gain an early appreciation of the nature of  
11     the interference and (2) do not constitute complete copies of any  
12     file. They are not part of the record of the interference and  
13     cannot be relied upon in the future merely because they are  
14     enclosed with this DECLARATION. If a party would like any of the  
15     following documents considered in the interference, the party  
16     should make the document an exhibit and offer the exhibit in  
17     evidence.

18  
19      Index of claims in application 09/512,810  
20      Claims 34-35, 37, 39, 45 and 47-59 of application 09/512,810  
21      Claim 46 of application 09/512,810  
22      U.S. Patent 5,824,538  
23      U.S. Patent 5,877,159  
24      U.S. Patent 6,531,313 B1  
25      RAM Fee History for U.S. Patent 5,877,159  
26      Bibliographic data  
27      Election and traverse filed 13 July 2001  
28      Office action entered 14 July 2004  
29      Response filed 17 August 2004  
30      Document transmitting suggestion for interference from  
31                Technology Center 1600 to the board dated 3 May 2005  
32                and received by the board on 9 February 2006  
33      Explanation, Cahn declartion and Exhibits 1 through 9  
34                related to Branstrom Rule 608(b) showing

1 cc (via overnight delivery) :

2  
3 Attorney for Branstrom  
4 (real party in interest  
5 United States of America  
6 as represented by the  
7 Secretary of the Army) :

8  
9 Office of the Staff Judge Advocate  
10 U.S. Army Medical Research and Materiel Command  
11 ATTN: MCMR-JA (Ms. Elizabeth Arwine)  
12 504 Scott Street  
13 Fort Detrick, MD 21702-5012

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24 Attorney for Powell  
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26 University of Maryland) :

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29 2100 Pennsylvania Avenue, N.W.  
30 Washington, D.C. 20037-3202

31  
32 Tel: 202-293-7060  
33 Fax: None  
34 Email: None

35  
36 Attorney for the United States [28 CFR § 0.45(f)] :

37  
38 Hon. John Fargo, Acting Director  
39 Commercial Litigation  
40 Civil Division  
41 U.S. Department of Justice  
42 Washington, D.C. 20530

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46 Room 11116  
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49 Tel: 202-514-7223  
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